UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASTRA AKTIEBOLAG, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC., ASTRAZENECA LP, Plaintiffs, v. ANDRX PHARMACEUTICALS, INC., Defendant.	99 Civ. 8926 99 Civ. 9887 **Opinion & Order** M-21-81 (BSJ) MDL Docket No. 1291

BARBARA S. JONES
UNITED STATES DISTRICT JUDGE

On November 21, 2008, Plaintiffs Astra Aktiebolag, Aktiebolaget Hässle, KBI-E, Inc., KBI, Inc., and Astrazeneca LP KBI-E, INC., KBI, INC., and Astrazeneca LP ("Plaintiffs" or "Astra") moved for leave to file a second supplemental complaint alleging additional facts relevant to assessing damages for infringement by Andrx Pharmaceuticals, Inc. ("Andrx") under 35 U.S.C. § 271(e)(2) and (e)(4). That same day, Andrx moved to amend and supplement its counterclaims ("Andrx's counterclaim motion"). Andrx has also moved for an order that Astra's claim of willful infringement is not part of this case, or, in the alternative, for judgment on the pleadings ("Andrx's willfulness motion"). For the reasons set forth below, Astra's motion to supplement is GRANTED, Andrx's counterclaim motion is DENIED, and Andrx's willfulness motion is DENIED.

BACKGROUND[1]

On May 21, 1998 and July 14, 1999, Astra filed complaints in the United States District Court for the Southern District of Florida, alleging, inter alia, that Andrx's Abbreviated New Drug Application ("ANDA") filing constituted infringement of several omeprazole patents belonging to Astra, including the formulation described in U.S. Patent Nos. 4,786,505 (the "'505 patent") and 4,853,230 (the "'230 patent"). On August 12, 1999, the Judicial Panel on Multidistrict Litigation transferred the actions, along with other actions concerning Astra's omeprazole patents, to the United States District Court for the Southern District of New York.

Shortly before and during the course of a bench trial, Astra discovered that Andrx had manufactured multiple batches of its ANDA product on a commercial scale (the "validation batches"). (Decl. of Alison Teh, Nov. 21, 2008, Exh. 8, 3245:3-16.) After consulting with the parties, the Court asked Andrx whether it wanted to delay trial to provide Astra with more discovery into the validation batches or whether it preferred to proceed with the trial limited to the ANDA product. Andrx chose the latter option, and the Court accordingly prohibited the parties from relying on evidence relating to those batches at

[1] For a more complete recitation of the facts and procedural history of this case, the reader is directed to the Court's decision dated October 16, 2002. See Astra Aktiebolag v. Genpharm Inc., 222 F. Supp. 2d 423 (S.D.N.Y. 2002).

trial. (Decl. of Alison Teh, Nov. 21, 2008, Exh. 10, 3137:18-19.)

On October 30, 2002, the Court entered a judgment finding that Andrx's ANDA product infringed certain '505 and '230 patent claims pursuant to 35 U.S.C. § 271(e)(2) and enjoining Andrx pursuant to 35 U.S.C. § 271(e)(4)(B) from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the omeprazole formulation described by its ANDA until on or before the expiration of the '505 and '230 patents. That same day, Andrx entered into a commercialization agreement with Kremers Urban Development Co. ("KUDCo"), pursuant to which Andrx agreed to relinquish its exclusivity rights obtained by filing the ANDA covering products infringing the '505 and '230 patents, in exchange for a share in the net profits on the sale of KUDCo's omeprazole formulation. (Decl. of Alison Teh, Nov. 21, 2008, Exh. 12.)

Andrx appealed the Court's judgment and on December 11, 2003, the United States Court of Appeals for the Federal Circuit affirmed the decision. See In re Omeprazole Patent Litig., Nos. 85-2443 & 85-2465, 2003 WL 22928641 (Fed. Cir. Dec. 11, 2003). At this point, the Court had not yet decided whether the '230 and '505 patents were unenforceable due to their connection to

U.S. Patent Number 6,013,281 (the "'281 patent"), which is also owned by Astra. On May 19, 2004, the Court issued a decision finding certain claims of the '281 patent infringed and invalid but rejecting Andrx's arguments that the claims of the '505 and '230 patents were unenforceable due to infectious unenforceability, unclean hands or litigation misconduct. See In re Omeprazole Patent Litig., No. M-21-81 (BSJ), 2004 U.S. Dist. LEXIS 9447, *49 (S.D.N.Y. May 19, 2004). Andrx appealed this decision as well, and on April 23, 2007, the Federal Circuit dismissed Andrx's appeal, rejecting Andrx's arguments regarding the unenforceability of the '505 and '230 patents. In re Omeprazole Patent Litig., 483 F.3d 1364, 1376 (Fed. Cir. 2007).

On July 25, 2007, Astra notified the Court and Andrx that because Andrx had publicly reported an inventory of generic omeprazole worth over $41 million (with an estimated sales value of over $400 million), Astra was entitled to damages. Noting that the Federal Circuit had affirmed the Court's ruling regarding Andrx's defenses to '505 and '230 patent infringement, Astra requested that the Court set a schedule to address pleading amendments and discovery regarding damages. (Decl. of Alison Teh, Nov. 21, 2008, Exh. 16, at 3.) In a subsequent letter dated August 7, 2008, Astra indicated that this issue remained outstanding. (Decl. of Alison Teh, Nov. 21, 2008, Exh.

18, at 6.) On November 21, 2008, Astra moved for leave to file a supplemental complaint alleging additional facts relating to its claim for damages against Andrx.

In Andrx's counterclaim motion, Andrx moves to amend and supplement its counterclaims to assert that Astra violated the Lanham Act, the Sherman Act, and state deceptive and unfair trade practices laws. In its willfulness motion, Andrx requests that the Court issue an order declaring that Astra's willfulness claim is no longer part of this case and, if Astra's motion to supplement is denied, that this litigation will terminate upon taxation of costs.

DISCUSSION

I. Astra's Motion to Supplement

Rule 15(d) of the Federal Rules of Civil Procedure allows a court, "[o]n motion and reasonable notice, . . . [and] on just terms" to permit the pleader to serve a supplemental pleading "setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). "A supplemental pleading may . . . be used to add additional facts or events relating to liability or to change the relief requested." 3 James WM. Moore et al., Moore's Federal Practice § 15.30 (3d ed. 2009). "The same principles that support the liberal amendment of pleadings also apply to

supplemental pleadings." Id. Therefore, "[a]bsent undue delay, bad faith, dilatory tactics, undue prejudice to the party to be served with the proposed pleading, or futility, the motion should be freely granted." Quaratino v. Tiffany & Co., 71 F.3d 58, 66 (2d Cir. 1995) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)). "Leave is normally granted, especially when the opposing party is not prejudiced by the supplemental pleading." Id.

Astra moves for leave to file a supplemental complaint that alleges additional facts supporting damages for Andrx's infringement. Astra contends that it could not have pled that Andrx manufactured, used and offered to sell validation batches because Andrx had not yet manufactured the batches at the time of Astra's pleadings. According to Astra, the proposed supplemental pleadings seek damages for previously pled and adjudged infringement; they do not set forth a new claim of infringement. In other words, "Andrx's commercial manufacture of the infringing ANDA product crystallized Astra's right to damages . . . for the same act of infringement that Astra previously brought before the Court." (Pls.' Reply Mem. at 12.)

In opposing Astra's motion, Andrx argues that (A) the Court's final judgment bars Astra from supplementing its complaint; (B) amendment would be futile because Astra's supplemental claims lack merit; and (C) Astra's motion is

untimely and the delay prejudices Andrx. The Court finds these arguments unpersuasive.

(A) Effect of the Court's Final Judgment

Andrx asserts that the Court's October 30, 2002 judgment bars Astra's motion to supplement because Astra has not moved to vacate or set it aside pursuant to Federal Rule of Civil Procedure 59(e) (motion to alter or amend a judgment) or 60(b) (motion for relief from final judgment), as required by Ruotolo v. City of New York, 514 F.3d 184, 191 (2d Cir. 2008). In Ruotolo, a First Amendment retaliation case, the Second Circuit stated that "[a] party seeking to file an amended complaint post-judgment must first have the judgment vacated or set aside pursuant to Fed. R. Civ. P. 59(e) or 60(b)." Id. (emphasis added). However, the Ruotolo plaintiff was attempting to amend his complaint post-judgment to plead a different instance of protected speech that occurred before plaintiff filed his original complaint. See id. Where a proposed pleading "deals with events that occurred before the filing of the original pleading," courts will not grant leave to supplement because the pleading is "in reality an amended pleading . . . ." 6A Charles Alan Wright et al., Federal Practice & Procedure § 1510 (2d ed. 2009). By contrast, there is no dispute that Astra seeks to supplement its complaint with a pleading setting forth an "event that happened after the date of the pleading to be

supplemented," Fed. R. Civ. P. 15(d) (emphasis added), i.e., Andrx's manufacture of the validation batches. Moreover, the Ruotolo plaintiff attempted to supplement his complaint to add a new theory of liability based on a distinct occurrence. See id. at 190 ("Ruotolo sought to plead another instance of speech that would not be vulnerable to the specific . . . analysis that had defeated [the prior] claim . . . ."). Here, by contrast, Astra has already proved its patents valid and infringed by Andrx's ANDA filing. Astra seeks only to supplement its complaint with respect to relief not encompassed in the judgment.

It is well-established that a district court "has discretion to hear a motion to file a supplemental pleading at any time during which the action is before it." 6A Charles Alan Wright et al., Federal Practice & Procedure § 1509 (2d ed. 2009). And "[t]he fact that the action was tried does not prevent the granting of a motion under Rule 15(d) . . . as the action is still pending." Otis Elevator Co. v. 570 Building Corp., 35 F. Supp. 348, 349 (S.D.N.Y. 1940) (granting motion for leave to file supplemental complaint alleging additional infringing acts after entry of judgment holding plaintiff's patent valid and infringed). Damages relief was not an issue at trial or one ready for resolution in October 2002, and it is therefore not precluded by the October 30, 2002 judgment. While the judgment precludes relitigation of infringement liability,

it does not preclude the possibility of additional remedies for that infringement.

(B) Futility of Supplementation

Next, Andrx argues that supplementation would be futile because Astra's supplemental claims lack merit. See Grace v. Rosenstock, 228 F.3d 40, 53 (2d Cir. 2000) ("[I]n determining whether leave to amend should be granted, the district court has discretion to consider, inter alia, the apparent futility of amendment." (internal quotation marks omitted)).

As a preliminary matter, Andrx contends that Astra's supplemental claim based on Andrx's commercialization agreement with KUDCo lacks merit because such agreements with ANDA first-filers are legitimate even when the first-filer's product would infringe an existing patent. However, Astra explains in its reply brief that its references to the KUDCo deal are not allegations of a separate act of infringement. Rather, Astra relies on the transaction as evidence of the value of Andrx's infringement and Astra's damages. (Pls.' Reply Mem. at 12.)

Next, Andrx asserts that Astra's new allegations of patent infringement would be time-barred because they occurred more than six years ago. See 35 U.S.C. § 286 (setting six year limitations period for infringement actions). Astra responds that the allegations would be timely, either because they do not impose new claims at all or because the allegations relate back

to the date of the original pleading. See Fed. R. Civ. P. 15(c)(1)(B) (providing that "[a]n amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction or occurrence set out . . . in the original pleading").

The Court agrees with Astra that the proposed supplemental allegations do not impose new claims. Instead, Astra seeks an additional remedy (damages) for the previously pled and adjudged infringement. An examination of the governing statutory scheme makes this clear:

> (e) . . .
> (2) It shall be an act of infringement to submit—
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.
> . . .
> (4) For an act of infringement described in paragraph (2)—
> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . , and
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within

> the United States or importation into the United States of an approved drug . . . .

35 U.S.C. § 271.

As the Supreme Court has explained, § 271(e)(2) creates "a highly artificial act of infringement that consists of submitting an ANDA . . . containing [a] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). In turn, § 271(e)(4) specifies the "consequences" of that artificial act of infringement. Id. Subsection (A) affects the effective date of the approval of the drug, subsection (B) provides for injunctive relief, and subsection (C) provides for damages where there has been commercial manufacture, use, offer to sell, or sale.

In its October 30, 2002 judgment, the Court found that Andrx's ANDA product infringed certain '505 and '230 patent claims under § 271(e)(2). Based on this finding, the Court enjoined Andrx pursuant to § 271(e)(4)(B) from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation of the omeprazole formulation described by its ANDA. Because the statute also provides that § 271(e)(2) infringement may give rise to damages when there is evidence of commercial manufacture, use, or sale, Astra now seeks to supplement its complaint with evidence of such

manufacture--i.e., evidence that Andrx manufactured validation batches of its ANDA product. As is clear from the statute, subsection § 271(e)(4)(C) is not an independent basis for a claim. Rather, it is one of the three enumerated "consequences" of a finding of infringement under § 271(e)(2). Because the Court agrees with Astra that the proposed supplemental allegations do not impose new claims, they are not time-barred.[2]

---

[2] Even if the proposed supplemental allegations are new claims, they would be timely under the relation back doctrine.

It is unclear "whether or under what circumstances a supplemental pleading will relate back to the date of the original pleading to avoid the effect of the governing statute of limitations." 6A Charles Alan Wright et al., Federal Practice & Procedure § 1508 (2d ed. 2009). This is because Rule 15(c)--which provides for the relation back of amended pleadings--makes no reference to supplemental pleadings, and Rule 15(d)--which governs supplemental pleadings--makes no reference to the relation back doctrine. Id. Nevertheless, courts have held that the doctrine applies to supplemental pleadings, particularly where "defendant had notice of the subject matter of the dispute and was not prejudiced in preparing his defense." Id. Because Andrx was aware that it had manufactured commercial-scale batches of its ANDA product, there is no indication that Andrx would be prejudiced in preparing its defense. The Court therefore finds that the relation back doctrine may apply to motions to supplement in certain circumstances, including those present here.

The Court further finds that to the extent Astra's supplemental allegations present new claims, they arise out of the same conduct set forth in the original and amended complaints and therefore relate back to the date of those pleadings. In its complaint, Astra alleged that Andrx's ANDA filing constituted infringement of several of Astra's omeprazole patents, in violation of 35 U.S.C. § 271(e)(2). That provision prohibits submitting an ANDA application "if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug." Id. (emphasis added). Astra thus alleged that Andrx filed its ANDA in order to commercially manufacture, use or sell generic omeprazole. Astra now alleges that Andrx ultimately obtained FDA approval of its omeprazole formulation and commenced commercial-scale production. In other words, the original complaint alleged that Andrx intended to commercially manufacture, use or sell the drug, and the supplemental pleadings allege that Andrx indeed did manufacture it. In this way, a claim for damages based on the actual "commercial manufacture, use, offer to sell, or sale . . . of an approved drug," 35 U.S.C. § 271(e)(4)(C), clearly arises out of the same conduct set forth in the original complaint.

That Andrx began production of the validation batches after Astra filed its complaint does not necessarily mean that the supplemental allegations are unconnected to the conduct originally alleged. By definition, a supplemental pleading always sets forth a transaction, occurrence or event that occurred

Andrx responds that if the proposed allegations are not new claims, then the final judgment finding and remedying Andrx's infringement of the '505 and '230 patents bar the allegations under the doctrine of res judicata. "Under res judicata, a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." San Remo Hotel, L.P. v. San Francisco, 545 U.S. 323, 336 n.16 (2005) (internal quotation marks omitted). As discussed earlier, the Court determined (with Andrx's consent) that it would limit Astra's suit to the ANDA product and exclude evidence of the validation batches. Those batches are, of course, the basis of Astra's supplemental allegations supporting its claim for damages under 35 U.S.C. § 271(e)(4). Thus, the issue of whether Andrx commercially manufactured, used, offered to sell, or sold the infringing drug was not raised earlier in the litigation, nor could it have been. Therefore, this Court's final judgment does not bar Astra's proposed supplemental pleadings under the doctrine of res judicata.

Andrx also argues that supplementation would be futile because Astra's new allegations fail on the merits. First,

---

after the date of the pleading to be supplemented, Fed. R. Civ. P. 15(d). Yet as discussed, courts apply the relation back doctrine to supplemental pleadings. Where, as here, the conduct alleged in supplemental pleadings arose out of the same conduct set forth in the original complaint, relation back is appropriate. Therefore, even if the proposed supplemental allegations are new claims, they are timely.

Andrx claims that Astra has failed to allege facts supporting the assertion in its proposed supplemental complaint that Andrx's manufacture of validation batches "is not exempted from infringement by 35 U.S.C. § 271(e)(1)." (Decl. of Alison Teh, Nov. 21, 2008, Exh. 1, ¶ 19(d).)[3] Given the admissions of Andrx's Chief Financial Officer that Andrx expected to generate millions of dollars in sales from the validation batches and took a $41 million charge to reserves as a result of the court's infringement decision, (Decl. of Alison Teh, Nov. 21, 2008, Exh. 13,) it is plausible that the validation batches were not made "solely for uses reasonably related" to the FDA approval process. 35 U.S.C. § 271(e)(1). In any event, this claim must await resolution on a future dispositive motion.

Second, Andrx argues that Astra incorrectly claims that the Court's findings of fact with respect to Andrx's ANDA product will automatically apply to the validation batches disclosed shortly before and during trial. In light of Andrx's statements at trial that there is no difference between its validation batches and the ANDA product, (Decl. of Alison Teh, Nov. 21, 2008, Exh. 10,) this argument is also better left for future resolution by a dispositive motion.

[3] That provision states that it is not "an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ." 35 U.S.C. § 271(e)(1).

Finally, Andrx contends that supplementation would be futile because Andrx never sold its omeprazole formulation and therefore Astra was never injured and can claim no royalties. This argument misses the mark. The statute clearly provides that damages may be awarded for an act of infringement if there has been "commercial manufacture, use, offer to sell, or sale," 35 U.S.C. § 271(e)(4) (emphasis added); see also Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1573 (Fed. Cir. 1996) ("The patent statute grants the patentee the right to exclude others from making, using, or selling the patented subject matter." (citing 35 U.S.C. § 271)(emphasis added)). Commercial manufacture alone suffices. General statements to the contrary in In re Apotex, Inc., 49 Fed. Appx. 902, 903 (Fed. Cir. Oct. 9, 2002) (unpublished) and Ortho-McNeil Pharms., Inc. v. Myland Labs., Inc., 267 F. Supp. 2d 545, 549 (N.D. W. Va. 2003) are dicta because in neither case did plaintiff seek damages based on alleged commercial manufacture of infringing products. See In re Apotex, 49 Fed. Appx. at 903 (noting that although plaintiff originally requested damages, plaintiff later "acknowledge[d] that there are no damages"); Ortho-McNeil Pharms., 267 F. Supp. 2d at 549 (reasoning that "because the parties agree that there have been no commercial sales of the alleged infringing levofloxacin tablets, the [damages] remedy of 35 U.S.C. § 271(e)(4)(C) is unavailable") (emphasis added).

Astra's damages claim is not futile because the patent statute sets the minimum quantum of damages as no less "than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 384. Where lost profits cannot be proved, courts determine a reasonable royalty rate "based upon the result of a hypothetical negotiation between the two parties at the time the infringement began." ResQNet.com, Inc. v. Lansa, Inc., 533 F. Supp. 2d 397, 416, 417 (S.D.N.Y. 2008) (noting that courts look to fifteen factors, including "[t]he amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement"). Such a calculation may well result in an award of damages to Astra.

For the foregoing reasons, the court concludes that supplementation would not be futile.

(C) Delay and Prejudice

Finally, Andrx argues that Astra has unduly delayed in filing its motion for leave to supplement and Andrx would be prejudiced by supplementation at this time. Andrx points out that Astra has known about Andrx's manufacture of an omeprazole product since before trial and Astra waited more than five years after the Court's October 2002 judgment to pursue damages.

"Leave to amend, though liberally granted, may properly be denied for: 'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.'" Ruotolo v. City of New York, 514 F.3d 184, 191 (2d Cir. 2008) (quoting Foman v. Davis, 371 U.S. 178, 182 (1963)). "Mere delay, however, absent a showing of bad faith or undue prejudice, does not provide a basis for the district court to deny the right to amend." State Teachers Ret. Bd. v. Fluor Corp., 654 F.2d 843, 856 (2d Cir. 1981); see also Glatt v. Chicago Park Dist., 87 F.3d 190, 194 (7th Cir. 1995) (noting that the same standard governs both amended and supplemental pleadings).

The Court finds that Astra has not unduly delayed in moving to supplement. As discussed earlier, the Andrx liability case was not complete through appeals until April 23, 2007, when the Federal Circuit affirmed the Court's May 19, 2004 decision and rejected Andrx's allegations that the claims of the '505 and '230 patents were unenforceable based on conduct relating to the '281 patent.[4] Shortly thereafter, on July 25, 2007, Astra requested that the Court set a schedule to address pleading

[4] If the Federal Circuit had reversed the Court's decision and held that the '281 patent rendered the '505 and '230 patents unenforceable, the Court's October 30, 2002 infringement ruling--which found claims of the '505 and '230 patents valid and infringed--would no longer provide a basis for the § 271(e)(4) damages that Astra now seeks.

amendments and discovery regarding damages. Astra later reiterated that request. Under these circumstances, the Court cannot conclude that Astra unduly delayed.

Moreover, there is no evidence of bad faith by Astra or prejudice to Andrx. Andrx claims that it would be prejudiced if supplementation is permitted because the evidence has been compromised: Andrx has been acquired by Watson Pharmaceuticals, Inc.; key employees with knowledge of relevant facts are no longer with Andrx or Watson; relevant documents are more difficult to retrieve; and the omeprazole capsules that Astra claims infringe have expired. (Def.'s Opp. Mem. at 21.) (citing Decl. of G. Michael Bryner, Dec. 2, 2008 ¶¶ 3-8.) However, the Bryner Declaration submitted in support of Andrx's claim of prejudice states only that certain individuals with relevant information are no longer employed by Andrx or Watson; it does not allege that these potential witnesses cannot be located. (Id. ¶¶ 3-5.) In addition, Bryner acknowledges reviewing a range of relevant records, including validation reports, validation protocols and manufacturing summaries, and he states that archived documents relating to the KUDCo deal can be located (although doing so would be "extremely burdensome"). (Id. ¶ 3.) On these facts, Andrx has not demonstrated evidentiary prejudice.

Finally, Andrx claims that its right to a jury trial has been compromised by Astra's tardy motion to supplement because Astra's equitable claims were already tried to the bench and Astra only now seeks damages. When Astra sought only equitable relief, Andrx reasons, Andrx could not insist on a jury trial. But if Astra had supplemented its complaints shortly before trial--when it learned that Andrx was manufacturing omeprazole products--Andrx would have been entitled to a jury trial (or Astra would have been forced to forgo its damages claim to ensure a bench trial).

The Court is unpersuaded that this amounts to cognizable prejudice. Until shortly before trial, Astra was unaware of evidence that Andrx had manufactured omeprazole, and so Astra pursued equitable relief only. Andrx agreed to proceed with a trial confined to the ANDA product. If the trial had been delayed to allow for discovery on the validation batches, Astra would have had an opportunity to supplement its complaints to pursue damages. Instead, Andrx chose to proceed, aware that a judgment finding Andrx's ANDA product infringing might result. Because the commercial manufacture of an infringing ANDA product is grounds for damages under § 271(e)(4)(C), Andrx knew or should have known that damages would be a possibility. Under these circumstances, there was no prejudice to Andrx's right to a jury trial.

For the reasons set forth above, Plaintiffs' motion for leave to file a second supplemental complaint is GRANTED.

II. Andrx's Counterclaim Motion

In Andrx's counterclaim motion, Andrx asserts that if Astra is granted leave to file a second supplemental complaint, Andrx is entitled to file new counterclaims in response. Andrx's proposed counterclaims allege that (1) Astra launched a deceptive marketing campaign that falsely promoted its Nexium product (which faced no generic competition) as clinically superior to Prilosec (which was about to face generic competition), and (2) Astra delayed the market entry of generic Prilosec by continuing a patent infringement suit against KUDCo. Andrx asserts that this conduct violated the Lanham Act, the Sherman Act, and state deceptive and unfair trade practices laws.

The Federal Rules of Civil Procedure provide that if the court permits a party to file a supplemental pleading, "[t]he court may order that the opposing party plead to the supplemental pleading within a specified time." Fed. R. Civ. P. 15(d). Andrx argues that if Astra is permitted to supplement its pleading, Andrx may then "plead to" that supplemental pleading by filing its amended and supplemental counterclaims as of right. (Def.'s Reply Mem. 4.) However, the authority on

which Andrx relies concerns pleadings in response to amended, not supplemented complaints. See Am. Home Prods. Corp. v. Johnson & Johnson, 111 F.R.D. 448, 453 (S.D.N.Y. 1986) (finding that "[w]hen AHP filed its amended complaint, McNeil was entitled as of right to file a responsive pleading") (emphasis added); Joseph Bancroft & Sons Co. v. M. Lowenstein & Sons, Inc., 50 F.R.D. 415, 419 (D. Del. 1970) ("Since the amending pleader chooses to redo his original work . . . he can hardly be heard to complain that [counter]claims filed against him are improper because they should have been asserted in response to his original pleading.") (emphasis added). By contrast, "[w]hether the adverse party will be directed to answer a supplemental pleading and what the time for doing so will be is a matter that is left to the trial court's discretion . . . ." 6A Charles Alan Wright et al., Federal Practice & Procedure § 1509 (2d ed. 2009); see Fed. R. Civ. P. 15(d) ("The court may order that the opposing party plead to the supplemental pleading within a specified time") (emphasis added); see also Refuse Fuels, Inc. v. Nat'l Union Fire Ins. Co. of Pittsburgh, 139 F.R.D. 576, 578 (D. Mass. 1991) (magistrate order) (explaining that if plaintiff's motion was construed as a motion for leave to amend the complaint defendants did not need court's leave to serve new counterclaims, but if the motion was a supplemental complaint under Rule 15(d) "no new counterclaims . . . would be

permitted unless they were in response to those portions of the pleadings which were supplemented"). Therefore, the Court will consider whether to exercise its discretion to permit Andrx to file its proposed counterclaims.

"A responsive pleading presumably will not be necessary when the supplemental pleading does not contain anything that deviates sharply from the earlier pleading. On the other hand, if a new party or claim is added by the supplemental pleading, a response often will be desirable." 6A Charles Alan Wright et al., Federal Practice & Procedure § 1509 (2d ed. 2009).

First, Andrx argues that if Astra is permitted to supplement its pleadings with allegations that Andrx profited from KUDCo's sale of KUDCo's omeprazole product, fairness requires that Andrx be permitted to file counterclaims revealing how Astra allegedly reduced Andrx's profits from that deal by continuing a patent infringement suit against KUDCo. But as already discussed, Astra's references to the KUDCo deal in the supplemental complaint are not allegations of a separate act of infringement but only evidence of the value of Andrx's previously-adjudicated infringement and Astra's damages. Because Astra's supplemental complaint adds no new claim relating to the KUDCo deal, the Court finds no reason to permit Andrx to file a counterclaim pertaining to that transaction.

Second, Andrx seeks leave to assert counterclaims alleging that Astra launched a deceptive marketing campaign that falsely promoted its Nexium product as superior to Prilosec, in violation of the antitrust laws and state deceptive and unfair trade practices laws. These allegations are unconnected to the subject matter of the patent infringement suit between Astra and Andrx. In addition, because Astra's supplemental pleadings do not impose new claims but merely seek an additional remedy for the previously-adjudicated infringement, Astra's supplemental complaint contains nothing "that deviates sharply from the earlier pleading." 6A Charles Alan Wright et al., Federal Practice & Procedure § 1509 (2d ed. 2009). Therefore, the Court finds no reason to permit Andrx to file a counterclaim pertaining to the alleged Nexium marketing scheme.

For these reasons, Andrx's counterclaim motion is DENIED.

III. Andrx's Willfulness Motion

Finally, Andrx requests that the Court issue an order declaring that Astra's willfulness claim is no longer part of this case and that, if Astra's motion to supplement is denied, this litigation will terminate upon taxation of costs. After the motion was filed, the Court "So Ordered" a stipulation and Order which resolved, inter alia, Astra's willful infringement claims. In light of this stipulation, Andrx's motion for an

order declaring that Astra's willfulness claim is no longer part of this case is DENIED as moot. In addition, because the Court grants Astra's motion for leave to supplement, Andrx's request that the Court tax costs in this action is DENIED as premature.

CONCLUSION

For the reasons set forth above, Astra's motion to supplement is GRANTED, Andrx's counterclaim motion is DENIED, and Andrx's willfulness motion is DENIED.

SO ORDERED:

Barbara S. Jones
UNITED STATES DISTRICT JUDGE

Dated: New York, New York
February 2, 2010